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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,669	11/05/1998	EDUARDO MARBAN	47728	3339

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/187,669	MARBAN, EDUARDO	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/06/2003 has been entered.

The response filed 11/6/2003 cancelled the pending claims and substituted new claims 32-46. Claims 32-46 are pending and under consideration in the instant application.

Double Patenting

Claims 37-42 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 32-36. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 37-42 comprise the same methods steps as claims 32-36. The fact that the preamble and stated outcome of the claims does not obviate the fact that the same method is being claimed in each case.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is directed to a method for predicting the pharmacological effect a drug candidate compound would have in a cell, tissue or organ that expresses a given protein wherein the expression level of the protein is modulated and a difference in phenotype between the test cells and suitable control cells is observed. The claim recites that observation of such a difference necessarily indicates the pharmacological effect of a candidate drug compound. Claim 37 is directed to a method of identifying a protein as a potential drug target protein and comprises the exact same methods steps as claim 32. Claim 32 recites that observation of a difference in phenotype for test cells compared to control cells means the protein whose expression has been modulated has been identified as a potential drug target. Because the preamble and conclusions for the two claims are different while the methods steps are the same, it is unclear what additional steps, if any are required to achieve the stated outcome for each claim.

Claim 32 is directed to a method for predicting the pharmacological effect of a drug compound in a cell, tissue or organ that expresses a given protein wherein the expression level of the protein is modulated and a difference in phenotype between the test cells and suitable control cells is observed. The claim recites that observation of such a difference necessarily indicates the pharmacological effect of a candidate drug compound. The claim is vague and indefinite, however, in that there is no explicit linkage between the candidate test compound and the targeted protein. It would be remedial to amend the claim to clearly indicate the candidate drug

compound would have the effect so long as it affected the functional activity of the protein whose expression is modulated in the recited method.

Claim 46 provides for the use of a potential drug target protein in a standard drug discovery strategy, but, since the claim does not set forth any steps involved in the further method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Moreover, it is unclear as to what constitutes a "standard" drug discovery strategy or process.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 46 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 46 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamb (U.S. Patent No. 5,955,275; see the entire patent).

Kamb teaches methods for identifying nucleic acid sequences that affect a cellular phenotype. The methods use a reporter gene whose level of expression correlates with the phenotype. An expression library is introduced into the cells and those cells exhibiting changes in reporter expression level are selected (e.g. Abstract). The expression library of the invention preferably expresses sequences encoding protein fragments, peptides or proteins that are termed "perturbagens" (column 3, lines 0-26). Host cells of the invention can be of several types, including human cells isolated from tissues and cancers (e.g. melanoma, colon cancer, etc.). Following expression, cells are selected based upon the decrease or increase in expression of the reporter protein (which can be considered a "target" polypeptide) upon expression of the library members (e.g. column 3, lines 20-26). The patent describes "perturbagens" as molecules that act in a transdominant mode to interfere with the function of endogenous cellular components. Perturbagens are typically proteinacious but may also be nucleic acids (e.g. antisense). Thus, the perturbagens of the patent can be considered "selected" or "target" proteins. Kamb teaches that one manner in which perturbagens can exert their effect is by forming a binding complex

between the wildtype target polypeptide and a perturbagen that is a fragment of the wildtype protein. Such a binding complex, comprising an altered form of the wildtype protein with the wildtype protein, is expected to behave in a manner similar to a small molecule inhibitor of the wildtype protein (e.g. Figures 1A-1C; columns 4-5, bridging paragraph). A perturbagen functioning in such a manner and selected for its ability to increase or decrease the expression of a reporter protein would necessarily be selected based upon its ability to "mimic" or "predict" the effect a drug compound. A perturbagen functioning in this manner would also necessarily constitute a "dominant negative" effect as defined in the specification (e.g. pages 12-13 of the instant specification-bridging paragraph). Kamb teaches that the perturbagen targets proteins are as interesting as the perturbagens themselves and can be readily identified by standard techniques (e.g. two-hybrid technologies) (e.g. column 15, lines 11-40).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

GERRY LEFFERS
PRIMARY EXAMINER

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636